

**GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS**

LOK SABHA
UNSTARRED QUESTION No. 4694
TO BE ANSWERED ON 28TH MARCH 2025

New Export Regulations in Pharmaceutical Sector

4694. Shri Azad Kirti Jha:

Will the Minister of **CHEMICALS AND FERTILIZERS** be pleased to state:

- (a) whether the Government has assessed the impact of the recent amendment requiring a product registration certificate from the importing country or approval from the Indian regulator for issuing export NOCs to the pharmaceutical sector;
- (b) if so, the details and outcome of the assessment, including its anticipated effects on the country's pharmaceutical exports, particularly on trade volume and market competitiveness;
- (c) whether the Government has considered the concerns raised by industry stakeholders regarding the potential trade diversion to other countries with less stringent regulations;
- (d) if so, the details thereof and whether the Government is considering any measures to safeguard the competitiveness of Indian pharmaceutical exports; and
- (e) whether the Government plans to review or modify the amendment in consultation with industry representatives, if so, the details thereof?

ANSWER

THE MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS

(SMT. ANUPRIYA PATEL)

(a) to (e): The Ministry of Health and Family Welfare has informed that in order to address recent concerns regarding export of unapproved drugs, the Central Drugs Standard Control Organisation (CDSCO) has initiated the process of issuing export No Objection Certificate (NOC) for unapproved drugs / approved new drugs based on product registration certificate from the National Regulatory Authority of the importing country or approval from the CDSCO, if the National Regulatory Authority is not available. These measures are aimed at ensuring smooth export operation for legitimate medicines to be used to support healthcare globally and strongly controlling illegal or unethical export of unapproved or potentially harmful drugs, with a view to address the root cause of problems related to export of unapproved drugs. The Ministry has further informed that no proposal to review or modify the same is under consideration or planned.
